UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Zykadia

Program	Prior Authorization
Medication	Zykadia™ (ceritinib)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	9/2014
Pharmacy and Therapeutics Approval Date	6/2020
Effective Date	8/2020

1. Background:

Zykadia™ (ceritinib) is a kinase inhibitor indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to Xalkori® (crizotinib). [1] The National Cancer Comprehensive Network (NCCN) also recommends Zykadia as first-line therapy for ALK-positive or ROS proto-oncogene 1 (ROS1)-positive recurrent or metastatic NSCLC and for the treatment of inflammatory myofibroblastic tumor (IMT) with ALK translocation.[2]

2. Coverage Criteria:

A. <u>Non-Small Cell Lung Cancer (NSCLC)</u>

1. <u>Initial Authorization</u>

a. **Zykadia** will be approved based on **<u>all</u>** of the following criteria:

(1) Diagnosis of non-small cell lung cancer (NSCLC)

-AND-

(2) **<u>One</u>** of the following:

(a) Disease is metastatic
(b) Disease is recurrent

-AND-

(3) **<u>One</u>** of the following:

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(a) Tumor is ALK-positive
(b) Tumor is ROS-1 positive

Authorization will be issued for 12 months.

2. Reauthorization

a. **Zykadia** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Zykadia therapy

Authorization will be issued for 12 months.

B. Soft Tissue Sarcoma

1. Initial Authorization

a. **Zykadia** will be approved based on the following criterion:

(1) Diagnosis of inflammatory myofibroblastic tumor (IMT) with ALK translocation

Authorization will be issued for 12 months.

2. Reauthorization

a. **Zykadia** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Zykadia therapy

Authorization will be issued for 12 months.

C. NCCN Recommended Regimens

1. Initial Authorization

a. **Zykadia** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

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2. Reauthorization

a. **Zykadia** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Zykadia therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Zykadia [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2019.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed May 7,2020.

Program	Prior Authorization - Zykadia (ceritinib)
Change Control	
Date	Change
9/2014	New policy
9/2015	Updated diagnosis verbiage and formatting from “diagnosis of metastatic non-small cell lung cancer” to “diagnosis of non-small cell lung cancer” and “disease is metastatic or recurrent”, per NCCN. Updated initial and reauthorization durations from 7 months to 12 months
6/2016	Updated policy to new template. Updated clinical criteria to align with Employer & Individual notification except less than 19 criteria.
6/2017	Updated background and removed requirement of crizotinib failure to align with NCCN recommendations
6/2018	Updated background and criteria to include first-line use for ROS-1 positive NSCLC. Added NCCN recommended review criteria. Updated references.
6/2019	Annual review with no change to coverage criteria. Updated

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	references.
6/2020	Annual review. Updated reference. Added Additional Clinical Rules.

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